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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,318	11/16/1999	PATRICIA L. CONKLIN	BTI-41	4166

20808 7590 01/08/2002

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EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	8

DATE MAILED: 01/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/441,318	CONKLIN ET AL.	
	Examiner	Art Unit	
	Annie R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

1. The amendments to the specification requested in Paper No. 7, filed 25 October, 2001, have been entered, as have the amendments to claims 1, 5-7, 12-14, 16 and 20-21, the cancellation of claim 23, and the addition of new claims 24-26. Claims 1-22 and 24-26 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

3. The amendments to the specification obviate the objections detailed in paragraphs 3-4 of the prior Office action.

4. The amendment to claims 1 and 16 to limit the enzymes to phosphoglucose isomerase, phosphomannomutase, GDP-mannose epimerase, GDP mannose pyrophosphorylase, and galactonolactone dehydrogenase obviates the rejections of claims 1-2, 5-8, 16-18 and 20-22 under 35 U.S.C. § 102(e) as being clearly anticipated by Trulson et al, claims 1-3, 5-8, 16, and claims 3 and 19 under 35 U.S.C. 103(a) as being unpatentable over Trulson et al in view of Schmidt et al.

5. The amendments to claims 1, 5-7, 12-14, 16 and 21 and the cancellation of claim 23 obviate the rejection of claims 1-8, 12-14, 16-19 and 21-23 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Claim Rejections - 35 USC § 112

6. Claims 1-22 remain rejected and 24-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated in the prior Office action for claims 1-23.

Applicant's arguments filed 25 October, 2001, have been fully considered but they are not persuasive. Applicant urges that the claims are enabled by the specification and that experimentation is allowed. Applicant urges that the claims are no longer drawn to overexpression of any gene in a plant. Applicant also urges that other genes encoding GMPase and other genes in the vitamin C pathway are well known in the art and that the sequence of GMPase (Accession No. T46645) can be found in GenBank. Applicant also urges that plants transformed with GMPase have increased levels of vitamin C relative to nontransformed plants (pg 13, line 24, to pg 17, line 3, of spec.).

This is not found persuasive because GenBank Accession No. T46645 is a 510 base long partial sequence of an *Arabidopsis* cDNA with numerous unidentified bases. This does not qualify as an enabling disclosure of the GMPase sequence. Deposit of the plasmid containing the gene used in the instant specification (e.g., g*VTC1*-pGPTV) under the rules detailed in the prior Office action would obviate this portion of the rejection.

The instant specification itself fails to teach the sequence of other genes in the vitamin C pathway, including phosphoglucose isomerase, phosphomannomutase, GDP-mannose epimerase, or galactonolactone dehydrogenase, or provide plasmids encoding these enzymes.

Page 13, line 24, to pg 17, line 3, of the specification describe the transformation of a GMPase gene into vtc1-1 **mutant** plants, and showing that the transformed plants have more vitamin C than the mutant plants. However, at no time are **wild-type** plants transformed with a GMPase gene or any of the other genes listed in claims 1 and 16. In light of the unpredictability associated with expression of gene in a plant, it has not a given that such plants would have increased vitamin C levels.

7. Claims 1-22 remain rejected and claims 24-26 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the prior Office action for claims 1-23.

Applicant's arguments filed 25 October, 2001, have been fully considered but they are not persuasive. Applicant urges that the genes encoding the enzymes of claims 1 and 16 are well-known in the art and the specification provides guidance for the sequence of GMPase.

This is not found persuasive because the sequence for the GMPase gene cited in the specification (GenBank Accession No. T46645) is a 510 base long partial sequence of an *Arabidopsis* cDNA with numerous unidentified bases, and the instant specification itself fails to teach the sequence of other genes encoding phosphoglucose isomerase, phosphomannomutase, GDP-mannose epimerase or galactonolactone dehydrogenase. Thus, the description is lacking as to the structural features that distinguish genes encoding these enzymes from other genes or other nucleic acids.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

8. Claims 1-22 and 24-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to limit the genes to ones encoding phosphoglucose isomerase, phosphomannomutase, GDP-mannose epimerase, GDP mannose pyrophosphorylase, and galactonolactone dehydrogenase. However, all of these are not the enzyme names are used in the specification. In the specification, "GDP-D-mannose-3,5-epimerase" is used instead of "GDP-

mannose epimerase", "GDP-D-mannose pyrophosphorylase" instead of "GDP mannose pyrophosphorylase", and "L-galactono-γ-lactone dehydrogenase" instead of "galactonolactone dehydrogenase" (see *e.g.*, the figure legend for Fig. 1 on pg 4). Thus, use of these terms constitutes NEW MATTER.

9. Claim 20 remains rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention, as stated in the prior Office action.

Dependent claims are included in the rejections.

Applicant's arguments filed 25 October, 2001, have been fully considered but they are not persuasive. Applicant urges that amendments to the claims obviate the rejections.

This is not found persuasive because claim 20 still recites "plant ... comprises increased antioxidation capacity". As stated in the prior Office action, a plant does not comprise increased antioxidation capacity, although increased antioxidation capacity may be a property of the plant. It is suggested that "comprises" be replaced with --has--.

Claim Rejections - 35 USC § 102

10. Claims 1-3, 5-8, 16, 18-22 remain rejected under 35 U.S.C. 102(a) as being clearly anticipated by Bauw et al, as stated in the prior Office action.

Applicant's arguments filed 25 October, 2001, have been fully considered but they are not persuasive. Applicant urges that the claims as amended exclude a gene encoding L-galactono-γ-lactone dehydrogenase.

This is not found persuasive because galactonolactone dehydrogenase and L-galactono-γ-lactone dehydrogenase are two names for the same enzyme.

11. Claims 4, 9-15 and 24-26 are free of the prior art, given the failure of the prior art to teach a gene encoding full-length GMPase and its expression in plants to increase vitamin C levels.

Conclusion

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula K. Hutzell, can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianeice Jacobs, at (703) 305-3388.

Anne R. Kubelik, Ph.D.
January 3, 2002

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